



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-598]

RIN 1117-AB60

Providing Controlled Substances to Ocean Vessels, Aircraft, and Other Entities

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is issuing this advance notice of proposed rulemaking to obtain information regarding the procurement of controlled substances by a medical officer for emergency kits on board ocean vessels, aircraft, and certain other entities. The regulations permitting controlled substances acquired by and dispensed under the general supervision of a medical officer to be stored in and dispensed from emergency kits on board ocean vessels, aircraft, and other entities were established in 1971 and have not been significantly modified since. DEA is considering revising these regulations and seeks to gain a better understanding of the industry's current needs and practices.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "RIN 1117-AB60/Docket No. DEA-598" on all correspondence, including any attachments.

- *Electronic comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776-2265.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by DEA for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase

“PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment.

You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as your name, address, etc.) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this advance notice of proposed rulemaking is available at <http://www.regulations.gov> for ease of reference.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act, as amended.¹ DEA publishes the implementing regulations for these statutes in 21 CFR parts 1300 to end. These regulations are designed to ensure a sufficient supply of controlled

¹ 21 U.S.C. 801-971.

substances for medical, scientific, and other legitimate purposes, and to deter the diversion of controlled substances for illicit purposes.

As mandated by the CSA, DEA establishes and maintains a closed system of control for manufacturing, distribution, and dispensing of controlled substances, and requires any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances to register with DEA, unless they meet an exemption.² The CSA authorizes the DEA Administrator (Administrator), by delegation from the Attorney General, to register an applicant to manufacture, distribute, or dispense controlled substances if such registration is determined to be consistent with the public interest.³ The CSA further authorizes the Administrator to promulgate regulations necessary and appropriate to execute the functions of subchapter I (Control and Enforcement) and subchapter II (Import and Export) of the CSA,⁴ or relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.⁵ By this authority, DEA is considering revising the regulations that permit controlled substances acquired by and dispensed under the general supervision of a medical officer to be stored in and dispensed from medicine chests, first aid packets, or dispensaries on board ocean vessels, aircraft, and in any other entity of fixed or transient location approved by the Administrator.⁶

Background

The existing regulations in 21 CFR 1301.25 that allow controlled substances to be held for stocking, maintained in, and dispensed from medicine chests, first aid packets, and dispensaries on board ocean vessels, aircraft, and in certain other entities were published in 1971 as part of the original regulations implementing the CSA.⁷ Since then, only minor

² 21 U.S.C. 822.

³ 21 U.S.C. 823.

⁴ 21 U.S.C. 871(b).

⁵ 21 U.S.C. 821.

⁶ 21 CFR 1301.25(a).

⁷ *Proposed Regulations Implementing the Comprehensive Drug Abuse Prevention Act of 1970*, 36 FR 4928 (March 13, 1971) and *Regulations Implementing the Comprehensive Drug Abuse Prevention Act of 1970*, 36 FR 7776 (April 24, 1971).

changes have been made to these regulations. In 1972, 21 CFR 301.28, “Registration regarding ocean vessels,” and 21 CFR 301.29, “Registration regarding commercial aircraft,” were combined into one section, 21 CFR 301.28, “Registration regarding ocean vessels, commercial aircraft and certain other entities.”⁸ In 1973, all parts and sections of Title 21 of the CFR were re-designated upward by one thousand; thus, 21 CFR 301.28 became 21 CFR 1301.28.⁹ In 1997, the section was re-designated again and became 21 CFR 1301.25.¹⁰ DEA is soliciting information from entities acquiring controlled substances in accordance with 21 CFR 1301.25 to better understand current industry practices.

Current Regulations

The current regulations allow controlled substances to be kept in emergency kits on board vessels, aircraft, and other entities if they are acquired by and dispensed under the general supervision of a medical officer or the master or first officer of certain vessels.¹¹ The regulations specify vessels as those engaged in international trade, in trade between ports of the United States, any merchant vessel belonging to the U.S. Government, and aircraft “operated by an air carrier under a certificate of permit issued pursuant to the Federal Aviation Act of 1958”¹² This language suggests that the regulations were intended to accommodate commercial entities. However, vessels and aircraft used primarily for recreation (e.g., private yachts, planes or jets) are not specifically addressed. Thus, DEA seeks information regarding emergency kits for recreational vessels and aircraft containing controlled substances acquired pursuant to the regulations in 21 CFR 1301.25. Specifically, DEA is seeking a detailed description of the circumstances in which controlled substances would be needed, the current process for obtaining controlled substances (e.g., through the use of a medical officer or directly from a pharmacy or distributor), and any recordkeeping

⁸ 37 FR 15917 (August 8, 1972).

⁹ 38 FR 26609 (September 24, 1973).

¹⁰ 62 FR 13938 (March 24, 1997).

¹¹ 21 CFR 1301.25(a).

¹² 21 CFR 1301.25(a).

procedures pertaining to the controlled substances in emergency kits on recreational vessels and aircraft.

DEA notes that all passenger-carrying aircraft certified by the Federal Aviation Administration are required to have an approved emergency medical kit on board.¹³ However, the list of contents required to be maintained in approved emergency medical kits does not include any controlled substances.¹⁴ Thus, DEA seeks information with regard to the maintenance of controlled substances in emergency kits on commercial aircraft.

The current regulations also allow controlled substances to be kept in emergency kits “in any entity of fixed or transient location approved by the Administrator. . . .”¹⁵ In a previously published notice of proposed rulemaking preamble, DEA stated that this provision was added to accommodate “other situations where controlled substances are held at scattered locations for emergency purposes: [o]ffshore oil rigs, landing fields in Alaska, remote industrial locations, and so forth.”¹⁶ DEA seeks information regarding controlled substances held in emergency kits at field sites of an industrial firm (e.g., airplane hangars, factories, mines, etc.), in oil rigs, platforms, barges, or any other technology related to offshore drilling and mining. Specifically, DEA is seeking a detailed description of the entity where the emergency kit is held, the process for obtaining controlled substances for the emergency kit, recordkeeping procedures, and controlled substance dispensing and administration requirements.

Medical Officers

The regulations require the medical officer to be licensed as a physician, employed by the owner or operator of the vessel, aircraft, or other entity, and registered with DEA at the principal office of the owner or operator of the vessel, aircraft, or other entity.¹⁷ The

¹³ 14 CFR 121.803(c).

¹⁴ 14 CFR part 121; Appendix A to part 121 – First Aid Kits and Emergency Medical Kits.

¹⁵ 21 CFR 1301.25(a)(3).

¹⁶ *Drug Abuse Prevention and Control Notice of Proposed Rule Making*, 37 FR 10370 (May 20, 1972) and *Drug Abuse Prevention and Control*, 37 FR 15917 (August 8, 1972).

¹⁷ 21 CFR 1301.25(b).

controlled substances must be ordered by the medical officer, who is the DEA registrant, and shipped to the registered location of the medical officer, as opposed to being shipped directly to the vessel, aircraft, or other entity. Representatives from the maritime industry have noted the challenges they face as a result of this requirement. In response to a previously published advance notice of proposed rulemaking (ANPRM),¹⁸ commenters reported that some medical officers are employed on a part-time basis and often serve as medical officers for more than one owner or operator. Commenters stated that this can result in significant delays and vessels being inadequately supplied, as controlled substances may sit at the medical officer's registered location for weeks. In addition, one commenter believed that the regulations do not provide any alternatives for fixed offshore installations with no medical officer to acquire controlled substances for emergency kits. However, DEA notes that for controlled substances, specifically those in schedule II, the regulations state that the controlled substances must be shipped only to the purchaser (*i.e.*, the medical officer) at the registered location.¹⁹ Therefore, DEA seeks information regarding a registration option for ocean vessels, aircraft, and other entities.

The regulations also provide that, in the absence of a registered medical officer, the master or first officer of a vessel may purchase controlled substances by personally appearing before a registered manufacturer, distributor, or authorized pharmacy.²⁰ The master or first officer must present proper identification and a written requisition for the controlled substances, prepared using the vessel's official stationery or purchase order form. In response to a previously published ANPRM, commenters opposed the requirement that the master or first officer must personally appear at the vendor's place of business, stating that it did not align with current industry practice.²¹ The commenters also noted that having the

¹⁸ 61 FR 49086 (September 18, 1996).

¹⁹ 21 CFR 1305.13(c).

²⁰ 21 CFR 1301.25(d).

²¹ 61 FR 49086 (September 18, 1996).

master or first officer go ashore to purchase controlled substances is difficult because of their shipboard duties and the length of time vessels are in port. DEA seeks information regarding the purchase of controlled substances by the master or first officer of a vessel. Specifically, DEA wishes to understand whether masters or first officers routinely go ashore to purchase controlled substances or only occasionally.

Comments Requested

DEA is soliciting information from the maritime and aviation and other industries to gain a better understanding of current industry practices, needs, and requirements with respect to controlled substances maintained in emergency kits. Although all comments are welcome, DEA is particularly interested in comments regarding the questions listed below.

1. Please describe in detail the procedures followed by vessels, aircraft, or any other approved entity to obtain controlled substances for medicine chests, first aid packets, or dispensaries.

2. Are there any other regulations, standards, or requirements (other than DEA regulations) that the entities must comply with when acquiring and maintaining controlled substances for medicine chests, first aid packets, or dispensaries?

3. Is a medical officer always involved in the procurement of the controlled substances? If not, please describe in detail: 1) the circumstances under which controlled substances are acquired without a medical officer, and 2) the process for acquiring controlled substances under such circumstances?

4. Please describe in detail the current role of a medical officer, including all services provided, on board vessels, aircraft, or any other approved entity.

5. Please describe in detail how controlled substances are acquired by those entities who do not employ a medical officer.

6. Who generally supplies the controlled substances to the vessels, aircraft, or other entities? DEA-registered distributors, pharmacies, manufacturers, etc.?

7. Please describe the safeguards that are in place to provide effective controls against diversion of controlled substances.

a. Please describe the procedures that must be followed when handling controlled substances.

b. Who has access to the controlled substances?

c. Who is permitted to dispense or administer controlled substances and under what circumstances are they permitted to do so?

d. Are there recordkeeping requirements for maintaining inventory, documenting any controlled substances administered, dispensed, lost, stolen, or disposed of?

e. Who is responsible for recordkeeping?

8. Please describe the procedures followed for disposing of damaged, expired, or otherwise unwanted controlled substances.

9. Please describe the procedure for reporting theft or loss of controlled substances.

10. Please provide any information that would help DEA quantify (or discuss qualitatively) the potential costs and benefits of a rule that would promote or restrict the use of contract and part-time medical officers.

11. Please provide any information that could be used to help DEA quantify (or discuss qualitatively) the potential costs and benefits of a rule that would require a DEA registration to obtain controlled substances for stocking, maintaining in, and dispensing from medicine chests, first aid packets, or dispensaries on board vessels, aircraft, or other entities.

12. For the airline industry: Please confirm whether controlled substances are kept in emergency kits on board airplanes.

a. If so, please describe how the controlled substances are obtained.

b. Are medical officers frequently employed by the airline industry?

c. If a medical emergency arises, who on the airplane is permitted to dispense or administer controlled substances, if needed?

13. For vessels and other offshore entities (e.g., oil rigs and platforms, mobile offshore drilling units, mining sites, etc.): How and when are the controlled substances delivered?

a. Are the controlled substances shipped from the medical officer to the vessel or other entity while in port or prior to offshore deployment?

b. Are controlled substances ever shipped directly from the vendor to the vessel or other entity?

c. Who on board the vessel or other entity is responsible for receiving the shipment?

Regulatory Analyses

This ANPRM was developed in accordance with the principles of Executive Order (E.O.) 12866, “Regulatory Planning and Review” and E.O. 13563, “Improving Regulation and Regulatory Review.” Since this action is an ANPRM, the requirement of E.O. 12866 to assess the costs and benefits of this action does not apply.

Furthermore, the requirements of the Regulatory Flexibility Act do not apply to this action because, at this stage, it is an ANPRM and not a “rule” as defined in 5 U.S.C. 601. Following review of the comments received in response to this ANPRM, if DEA proceeds with a notice of proposed rulemaking regarding this matter, DEA will conduct all relevant analyses as required by statute or Executive Order.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 13, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Scott Brinks,
Federal Register Liaison Officer,
Drug Enforcement Administration.

[FR Doc. 2022-15265 Filed: 7/15/2022 8:45 am; Publication Date: 7/18/2022]